WHAT IS CLAIMED IS:

1   1. A method for controlling electronic records produced by an application

2   software program for an analytical laboratory apparatus, wherein the program and

3   apparatus are used by designated users performing assigned user roles, said

4   method comprising:

5   (a) restricting access to the application software program to the designated users

6   through a user authentication;

7   (b) assigning a set of user rights to each user role, wherein said designated users

8   are divided into a first group of users who are given a right to sign the electronic

9   records and a second group who are denied the right to sign the electronic

10   records;

11   (c) storing the electronic records in a protected data file format;

12   (d) maintaining a history of access entries and activities performed in the application

13   software program; and

14   (e) authenticating the electronic records by means of at least one electronic

15   signature by one of the users of the first group, wherein access to step (e) of the

16   method is denied to users of the second group.

1   2. The method of claim 1, wherein the method conforms to a set of

2   requirements issued by the U.S. Federal Food and Drug Administration (FDA) and

3   known as "Title 21, CFR Part 11 - Electronic Records; Electronic Signatures".

1   3. The method of claim 1, wherein access to step (e) is subject to an

2   additional user authentication.

1   4. The method of claim 1, wherein the at least one electronic signature

2   comprises a plurality of electronic signatures, wherein a signature meaning is

3   attached to each of said plurality of electronic signatures, said signature meaning

4   being selected from a list of signature meanings, wherein the signature meaning

5   indicates a signature status that an electronic record will have as a result of an

6   electronic signature, and wherein each signature meaning in said list is correlated

7   with a signature level in a hierarchy ascending from a lowest to a highest signature

8   level, so that each of said plurality of electronic signatures is hierarchically ranked by

9   way of its attached meaning.

1   5. The method of claim 4, wherein the hierarchically ranked meanings

2   include at least one of the meanings "Tested", "Reviewed", "Approved", and

3   "Released".

1   6. The method of claim 4, wherein each user of the first group is

2   assigned a maximum signature level that is selected from the signature levels in said

3   list, and wherein said user is not allowed to attach to his/her signature a signature

4   meaning that exceeds said user's assigned maximum signature level.

1   7. The method of claim 6, wherein said maximum signature level is

2   assigned to a user in accordance with the user role performed by said user.

1   8. The method of claim 6, wherein when the electronic record has already

2   been signed at least once, said user is not allowed to attach to his/her signature a

3   signature meaning that ranks lower than the signature status which the electronic

4   record has as a result of said at least one previous signature.

1   9. The method of claim 6, wherein when the electronic record has already

2   been signed at least once, said user is not allowed to attach to his/her signature a

3   signature meaning that does not rank at least one level higher than the signature

4   status which the electronic record has as a result of said at least one previous

5   signature.

1   10. The method of claim 6, wherein said user is only allowed to attach to

2   his/her signature a signature meaning exactly one level higher than the signature

3   status which the electronic record has as a result of said at least one previous

4   signature, so that said plurality of signatures follow each other in consecutive

5   ascending order of signature level.

1   11. The method of claim 4, wherein a record is fully authenticated after a

2   prescribed number of signatures comprising at least two different signature levels

3   have been attached to said record.

1   12. The method of claim 11, wherein the at least two different signature

2   levels comprise a prescribed hierarchically ascending series of signature levels.

1   13. The method of claim 1, wherein step (e) comprises attaching a

2   remark to the electronic signature.

1   14. The method of claim 4, wherein the signature levels attached to the

2   signature meanings in said list from the lowest to the highest level are consecutive

3   ascending numbers starting at the number one.

1   15. The method of claim 4, wherein the signature levels attached to the

2   signature meanings in said list from the lowest to the highest level are non-

3   consecutive ascending numbers, leaving unused numbers available for additional

4   intermediate signature levels.

1   16. The method of claim 6, wherein parts (a) and (b) of the method are

2   performed by a system administrator.

1   17. The method of claim 16, wherein said parts (a) and (b) include at

2   least one of:

3   -   assigning user names and passwords to the designated users,

4   -   retiring said user names and passwords,

5   -   assigning the maximum signature level to each user account, and

6   -   defining the signature meanings and ranking them according to signature levels.

1   18. An application software program that implements a method for

2   controlling electronic records in an analytical laboratory apparatus, wherein the

3   method comprises a signing procedure for authenticating the electronic records with

4   a plurality of electronic signatures, with the following steps:

5   (a)   designating a first group of users who are given a right to sign the electronic

6   records and a second group of users who are denied the right to sign the

7   electronic records;

8   (b)   restricting access to the signing procedure to the users of the first group

9   through a verification routine in said application software program;

10   (c)   establishing a list of signature meanings to be attached to the electronic

11   signatures, wherein each signature meaning in said list is ranked according to a

12   signature level defined as an ordinal number;

13   (d)   assigning to each user of the first group a maximum signature level; and

14   (e)   controlling said signing procedure so that the user can sign a record only with a

15   signature meaning that ranks not lower than any previous signature attached to

16   the record and not higher than the user's maximum signature level.

1   19. The application software program of claim 18, wherein step (e)

2   comprises controlling said signing procedure so that the user can sign a record only

3   with a signature meaning that ranks higher than any previous signature attached to

4   the record, but not higher than the user's maximum signature level.